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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/514,312	02/28/00	KASAI	T 31671-157328

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Washington DC 20043-9998

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EXAMINER

DI NOLA BARON, L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/514,312	Applicant(s) KASAI ET AL.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- Th **MAILING DATE** of this communication appears n th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of Applicants amendment, filed on February 23, 2001.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15, 17, 20, 22, 24, 27, 29, 30, 33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Provonchee et al.

The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and to a coated material comprising said coating agent.

Provonchee et al. discloses polysaccharide compositions of the gel-forming beta-1,3-glucan type and methods of preparing and using said polysaccharides (See e.g., col. 1, lines 6-14).

Provonchee et al. teaches that the beta-1, 3-glucan polysaccharides of the invention are widely distributed in nature as components of yeast cell walls (See e.g., col. 1, lines 15-35). Provonchee et al. describes the Critical Temperature Neutralization (CTN) method for preparing solutions and gels of the invention and teaches that the beta-1, 3-glucan polysaccharides are separated from a culturing method by known methods, heated and the pH of the solution is neutralized by addition of an acid (See e.g., col. 4, lines 4-66). Provonchee et al. teaches that the CTN method makes possible applications such as microencapsulation and formation of biodegradable therapeutic agent microcarriers (See e.g., col. 8, lines 53-68). Additionally, Provonchee et al.

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teaches that the gels of the invention may be used for controlled release of pharmaceuticals, preparation of food and coating of seeds, embryos, plantelets and the like (See e.g., col. 9, lines 1-39).

The compositions and methods disclosed by Provonchee et al. meet the limitations of claims 15, 17, 20, 22, 24, 27, 29, 30, 33 and 36 of the instant application, as they contemplate a coating agent comprising yeast cell wall fractions and a coated material comprising said coating agent. Thus, Provonchee et al. anticipates the claimed invention.

3. Claims 15, 17, 20, 22, 24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Shank.

The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and to a coated material comprising said coating agent.

Shank provides a product, such as a drug, condiment or vitamin, encapsulated within biological capsules provided by microorganisms, such as yeast (See e.g., col. 1, line 46 to col. 2, line 51).

Shank teaches that the yeast cell wall may be softened by treatment with proteolytic enzymes, and then hardened with dilute aldehydes (See e.g., col. 5, lines 28-50). In the examples provided, Shank teaches that the encapsulated material is cast upon an acidified paper (See e.g., Examples I-V).

The compositions and methods disclosed by Shank meet the limitations of claims 15, 17, 20, 22, 24 and 27 of the instant application, as they contemplate a coating agent comprising yeast cell wall fractions and a coated material comprising said coating agent. Thus, Shank anticipates the claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Provonchee et al., as applied to claims 15, 17, 20, 22, 24, 27, 29, 30, 33 and 36 above, in view of Jamas et al. The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and a plasticizer and to a coated material comprising said coating agent.

The teachings of Provonchee et al. have been summarized above. Provonchee et al. does not include a plasticizer in the compositions of the invention.

Jamas et al. provides a composition and method utilizing yeast glucan as a dietary additive and explains that beta-glucans are the alkali-insoluble portion obtained from yeast cell walls (See e.g., col. 3, line 1 to col. 4, line 10). Jamas et al. teaches that the glucans can be treated with hydrolytic enzymes or an acid after extraction from yeast to decrease viscosity and increase water holding capacity (See e.g., col. 5, lines 11-62). Jamas et al. teaches that the dietary additive of the invention can be administered orally, the glucan can be administered alone or with other ingredients and the compositions of the invention can be in the form of tablet or powder and include additives, such as a plasticizer (See e.g., col. 6, line 66 to col. 7, line 20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Provonchee et al., by adding a plasticizer and administer the composition in the form of tablet, as taught by Jamas et al. One of

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ordinary skill in the art would have been motivated to make such a modification to further control the release of the coated material. Because of the teachings of Jamas et al., that beta-glucan may be combined with a plasticizer, one of ordinary skill in the art would have a reasonable expectation that the coating agent claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

6. Claims 15-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shank in view of Jamas et al. The claimed invention refers to a coating agent comprising acid-treated yeast cell wall fractions and a plasticizer and to a coated material comprising said coating agent. The teachings of Shank have been summarized above (See 35 U.S.C. 102(b) rejection to claims 1, 2, 4, 6, 7, 10, 12 and 13). Shank does not include a plasticizer in the compositions of the invention. The teachings of Jamas et al. have been summarized above (See 35 U.S.C. 103(a) rejection of claims 1-14).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions and methods disclosed by Shank, by adding a plasticizer and administer the composition in the form of tablet, as taught by Jamas et al. One of ordinary skill in the art would have been motivated to make such a modification to further control the release of the coated material. Because of the teachings of Jamas et al., that beta-glucan may be combined with a plasticizer, one of ordinary skill in the art would have a reasonable expectation that the coating agent claimed in the instant application would be

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successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments filed on February 23, 2001 have been fully considered but they are not persuasive.

8. In response to Applicants argument, that the prior art (Provoncee et al.) discloses pseudo-plastic gels, it is noted that pseudo-plastic is still considered plastic and gels are fluid.

9. In response to Applicants argument, that the prior art discloses coating agents with different solubility, pH dependency and oxygen permeability, it is noted that the limitations Applicants refer to are not in the claims. Furthermore, Applicants have not shown the criticality of said limitations for Applicants purpose.

10. In response to Applicants argument, that the prior art (Shank) teaches microencapsulation, it is noted that Applicants claimed invention uses the term "comprising". Said term permits encapsulation, as disclosed by the prior art.

11. In response to Applicants argument, that the prior art (Jamas et al.) does not suggest that glucan is a coating agent, it is noted that the prior art discloses glucan compositions comprising a coating material, such as a plasticizer, rendering obvious the combination of the two elements (See e.g., col. 7, line 20).

12. In response to Applicants argument, that the prior art does not teach dissolution control, it is noted that such a limitation is not in the claims and is not a requirement.

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13. In response to applicant's argument against the combination of the prior art, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Claims 15-37 are rejected.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

March 21, 2001


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600